

## INSTALLATION & TRAINING REPORT

Customer Name : Dagan Diagnostic Centre.  
Department : Laboratory  
Address : opp. Civil Hospital, Palwal.  
City : Palwal Pin : 121102 State : Haryana.  
Territory : D-10 Zone : NZI  
Telephone & Fax : 01275-250877 email : jogenden.dagan@gmail.com.  
Contact Person : Mr. Joginder Dagan. MobileNo. : 7015830951  
Instrument Model: EM-360 Sr. No. : 601070  
Installation Date : 03-01-2022

The above mentioned instrument has been satisfactorily installed by Service Engineer / Product Specialist of Transasia Bio-Medicals Ltd. Operational Training & User Maintenance of the instrument was provided to the following staff members on date (s) : 03-01-2022

Name (s)	Designation/ Dept.
1. <u>Mr. Joginder</u>	<u>Owner.</u>
2. <u>Mrs. Rajeswari</u>	<u>Lab Tech.</u>
3. _____	_____

Test/ Parameters Demonstrated : LFT, KFT

Customer Comments (If any): Instrument is working fine.

Engineer / Product Specialist : \_\_\_\_\_

Signature : Amol / Deveder / Ravi

Name : Mr. Amol / Mr. Deveder / Mr. Ravi

Date : 03-01-2022

Customer Signature : Joginder

Customer Name : Mr. Joginder Dagan.

Designation : Owner.

Customer Seal : \_\_\_\_\_

### Arbitration Clause

All disputes, Differences, controversies and questions directly or indirectly arising at any time under, out of, in connection with or in relation to the payment of this instrument / reagents / service shall be referred to the sole arbitrator to be appointed by Transasia Bio-Medicals Limited under the Arbitration and Conciliation Act 1996. The venue and seat of arbitration shall be at Mumbai. The award rendered by the arbitrator(s) shall be final and binding upon both Parties.

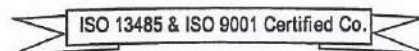
www.transasia.co.in

**TRANSASIA BIO-MEDICALS LTD.**

TRANSASIA HOUSE, 8 CHANDIVALI STUDIO ROAD, ANDHERI (E), MUMBAI - 400 072. TEL : 4030 9000 FAX : (022) 4030 9090 / 2857 3030 Email : transasia@transasia.co.in

DELHI (011) 25732223 CHENNAI (044) 28227149 KOLKATA (033) 22157839 BANGALORE (080) 25568044 AHMEDABAD (079) 26407030

Doc No. SCOO-430/ISS-4




H. O. COPY

# Result Reprint

Report Type : Controls      03-Jan-2022

Sr #	Lot #	Consumable	Test	Result Unit	Flag	Curve #	Result Date	Mean	SD	Interval (3SD)
1	26491	BIO RAD 1	GPThL	23.4 U/L	-1SD	61	3-Jan-2022 14:52:13	27.400	2.700	19.3 - 35.5
2	26491	BIO RAD 1	ALPU	113 U/L		62	3-Jan-2022 14:52:23	115.000	12.000	79 - 151
3	26491	BIO RAD 1	GGT	64.1 U/L		63	3-Jan-2022 14:52:33	66.300	6.600	46.5 - 86.1
4	26491	BIO RAD 1	BIDD	0.38 mg/dl		64	3-Jan-2022 14:52:43	0.370	0.040	0.25 - 0.49
5	26491	BIO RAD 1	BIT	0.91 mg/dl		65	3-Jan-2022 14:52:53	0.990	0.120	0.63 - 1.35
6	26491	BIO RAD 1	UREA	35.2 mg/dl		66	3-Jan-2022 14:53:02	33.800	2.550	26.15 - 41.45
7	26491	BIO RAD 1	TRIG	178.2 mg/dl		67	3-Jan-2022 14:53:12	182.000	13.500	141.5 - 222.5
8	26491	BIO RAD 1	CHOL	241 mg/dl		68	3-Jan-2022 14:53:22	251.000	19.500	192.5 - 309.5
9	26491	BIO RAD 1	UA	5.1 mg/dl		69	3-Jan-2022 14:53:32	5.380	0.400	4.18 - 6.58
10	26491	BIO RAD 1	ALBD	3.74 g/dl		70	3-Jan-2022 14:53:41	3.960	0.300	3.06 - 4.86
11	26491	BIO RAD 1	CRENZ	1.67 mg/dl		77	3-Jan-2022 15:04:28	1.660	0.160	1.18 - 2.14
12	26491	BIO RAD 1	HDLC	69.4 mg/dl		84	3-Jan-2022 16:03:44	67.200	6.750	46.95 - 87.45
13	26491	BIO RAD 1	CA	9.8 mg/dl		91	3-Jan-2022 16:04:53	9.210	0.690	7.14 - 11.28

<b>TRANSASIA BIOMEDICALS LIMITED</b>				
<b>INSTALLATION QUALIFICATION FOR DAGAR DIAGNOSTIC CENTER PALWAL 121102</b>				
<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>	

## 5.0 INSTRUMENT DESCRIPTION

The Clinical Chemistry Analyzer is an open, full automated, discrete, patient prioritized, random access, computerized analyzer.

### Technical Specifications:

System Type	Open, Automated, Discrete, Random Access, Patient Prioritized, Clinical Chemistry Analyzer
Analysis Speed	360 Biochemistry tests per hour 600(with ISE)
Display resolution	800 x 600
Analyzer Dimensions	840 (W) x 610 (D) x 1100 (H) mm
Number of tests on board	Maximum: 50
Assay Modes	1-point, 2-point, Rate-A and Rate -B
Calibration	Linear (two point and multi point), Factorized and Non-linear multipoint
Sample (Tubes / Cups)	Primary tubes of 5, 7 or 10mL & sample cups
Photometric Optics	Mono and Bi-chromatic measurement using holographic diffraction grating and 12 wavelengths
Absorbance Range	0 – 2.5
Auxiliary Data	10,000 results
Interface	RS-232 C port for Bi-directional Communication
Stat Sampling	Total 25 position(E1-E20 standard positions on standard tray & E46-E50 on sample disk outer ring.

<b>TRANSASIA BIOMEDICALS LIMITED</b>				<b>TRANSASIA<sup>®</sup></b> Bio-Medicals Ltd.
<b>INSTALLATION QUALIFICATION FOR DAGAR DIAGNOSTIC CENTER PALWAL 121102</b>				
<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>	

**Purpose:**

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, Cholestrol, Tri-glycerides, Proteins, etc.

The working unit of the analyzer comprises the following:

- Basic operating unit with an intelligent photometer
- Sophisticated robotics combined with an operating console and a central processing unit (CPU).

**Operating Unit:**

The operating unit of the analyzer includes the sample and reagent handling systems. The sample handling system consists of a sample tray, sample arm, sample syringe and a wash station for the sample probe.

**Photometric System:**

The photometric system consists of 60 hard glass cuvettes, a high-resolution diffraction grating (with 12 user selectable wavelengths) and a halogen lamp.

**Operating Console:**

The operating console consists of a touch screen (optional) color monitor, a key board and a mouse.

**CPU (Central Processing Unit):**

CPU consists of Pentium – IV 1.7 GHz processor (or Higher) with a 48 x CD Drive, and minimum 256 MB memory. The application software can be installed on computers with operating systems of Windows XP.

Besides the above mentioned, this analyzer has got the unique Software and Hardware features.

<b>TRANSASIA BIOMEDICALS LIMITED</b>				<b>TRANSASIA<sup>®</sup></b> Bio-Medicals Ltd.
<b>INSTALLATION QUALIFICATION FOR DAGAR DIAGNOSTIC CENTER</b>				
<b>PALWAL 121102</b>				
<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>	

## 6.0 IDENTIFICATION OF MAJOR COMPONENTS / ACCESSORIES


Details of each major component identified in this section, is recorded in a data sheet under the section 08.0.

Name of Component / Accessories	Present	Verified by Signature	Observations
	Yes / No		
Sample Tray / Disk	Yes	Devender Singh	N/A
Sample Syringe	Yes		
Sample Probe	Yes		
Wash Station for Sample Probe	Yes		
Reagent Tray / Disk	Yes		
Reagent Bottles	Yes		
Reagent Probe	Yes		
Reagent Syringe	Yes		
Stirrer	Yes		
Permanent Reaction Cuvette	Yes		
7 Stage Laundry System	Yes		
Light Source	Yes		
Sample Cups	Yes		
Software of EM 360	Yes		

<b>TRANSASIA BIOMEDICALS LIMITED</b>			<b>TRANSASIA</b> <sup>®</sup> Bio-Medicals Ltd.
<b>INSTALLATION QUALIFICATION FOR DAGAR DIAGNOSTIC CENTER PALWAL 121102</b>			
<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b> 601070	

### 7.0 INSTALLATION CHECK / REVIEW

S. No.	Statement	Yes / No	Verified by Signature
1.	Verify that the "as built" drawings are complete and represent the design concept	Yes	Devender Singh
2.	Verify that major components / accessories are securely anchored and shock proof.		
3.	Verify that there is no observable physical damage.		
4.	Verify that there is sufficient room of servicing provided		
5.	Verify that all utilities and electrical connections have been done according to the drawings.		
6.	Walking access to ground mounted instrument provided.		
7.	Required electric connections are tight, weather proof and earthed.		
8.	Instrument identification nameplate visible.		
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.		
10.	Verify that the instruments installed and leveled properly on the floor.		
11.	Verify that the Material of Construction is proper and meeting the requirements.		

<b>TRANSASIA BIOMEDICALS LIMITED</b>				
<b>OPERATIONAL QUALIFICATION CHECKLIST FOR DAGAR DIAGNOSTIC CENTER PALWAL 121102</b>				
<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>	

As part of Operational qualification, the following checks shall be done and each test shall be recorded:

**Instrument Start-up**

To check and establish the standard sequence to be followed, during start-up of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

**Functional Checks**

To check and ensure that different functions (such as switching devices, indication / monitoring / recording devices, feedback system, etc.) for correct operation of the subjected instrument are working as expected.

**Interlocks and Alarms Check**

To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

**Safety / Security Checks**

To check and ensure that the safety / security functions (such as program logging, process control, personnel safety systems, password check, etc.) to protect the instrument and personnel are working as expected.

**Instrument Shut-down**

To check and establish the standard sequence to be followed, during shut-down of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

**TRANSASIA BIOMEDICALS LIMITED**

**OPERATIONAL QUALIFICATION CHECKLIST FOR DAGAR DIAGNOSTIC CENTER PALWAL 121102**



<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>
---------------------------------	------------------------------------	----------------------	---------------

**1.0 INSTRUMENT START-UP:**

Refer the Operator's Manual for the procedures, for the following activities:

<b>Action</b>	<b>Observation</b>	<b>Verified by Sign</b>	<b>Remarks</b>
Ensure that all the required electrical connections are properly connected.	OK	Devender Singh	N/A
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	OK	Devender Singh	N/A
Ensure the availability of XL Wash.	OK	Devender Singh	N/A
Ensure the availability of Biohazard Waste.	OK	Devender Singh	N/A
Ensure the availability of Normal Waste.	OK	Devender Singh	N/A
Switch ON the rear switch of the analyzer.	OK	Devender Singh	N/A
Switch ON the side switch of the analyzer.	OK	Devender Singh	N/A
Switch ON the computer and start the analyzer application software.	OK	Devender Singh	N/A
Initialization	OK	Devender Singh	N/A



<b>TRANSASIA BIOMEDICALS LIMITED</b>			<b>TRANSASIA<sup>®</sup></b> Bio-Medicals Ltd.
<b>OPERATIONAL QUALIFICATION CHECKLIST FOR DAGAR DIAGNOSTIC CENTER PALWAL 121102</b>			
<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b> <b>601070</b>	

**2.0 FUNCTIONAL CHECKS:**

**2.1 Maintenance:**

Refer the Operator's Manual for the procedures, for the following activities:

<b>Activity</b>	<b>Observation</b>	<b>Verified by Sign</b>	<b>Remarks</b>
Photometer functioning	OK	Devender Singh	N/A
Cuvette Rinse	OK	Devender Singh	N/A

**TRANSASIA BIOMEDICALS LIMITED****OPERATIONAL QUALIFICATION CHECKLIST FOR DAGAR DIAGNOSTIC  
CENTER PALWAL 121102****TRANSASIA**<sup>®</sup>  
Bio-Medicals Ltd.

<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>
---------------------------------	------------------------------------	----------------------	---------------

**2.2 Loading of Reagents:**

Refer the Operator's Manual for the procedures, for the following activities:

<b>Action</b>	<b>Observation</b>	<b>Verified by Sign</b>	<b>Remarks</b>
Reagent Level Scan, Dead Volume Check & 2 Reagent Chemistry	OK	Devender Singh	N/A

<b>TRANSASIA BIOMEDICALS LIMITED</b>				<b>TRANSASIA</b> <sup>®</sup> Bio-Medicals Ltd.
<b>PERFORMANCE QUALIFICATION FOR DAGAR DIAGNOSTIC CENTER PALWAL 121102</b>				
<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>	

**2.0 OBJECTIVE**

The objective of this protocol is to establish documented evidence for the Performance Qualification of EM360 (Bio-Chemistry Random Analyzer) at **Dagar Diagnostic Center, Palwal 121102** and Transasia Biomedicals Ltd. to ensure that the results obtained are within the pre-determined Acceptance Criteria.

**3.0 SCOPE**


The Scope of this protocol is applicable to EM360 (Bio-Chemistry Random Analyzer).

**4.0 PRE-REQUISITES:**

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification prior to PQ.
- Completion of Operational Qualification prior to PQ.

**5.0 EXECUTION TEAM**

Name	Department	Designation	Signature
Ravi Kumar Sah	TSD	Application Specialist	

**TRANSASIA BIOMEDICALS LIMITED**


**PERFORMANCE QUALIFICATION FOR DAGAR DIAGNOSTIC CENTER  
PALWAL 121102**



<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>
---------------------------------	------------------------------------	----------------------	---------------

**6.0 TEST PLAN**


5-6 tests of different mode shall be followed, during the Performance Qualification of EM360 (Bio-Chemistry Random Analyzer).

<b>TRANSASIA BIOMEDICALS LIMITED</b>				
<b>PERFORMANCE QUALIFICATION FOR DAGAR DIAGNOSTIC CENTER PALWAL 121102</b>				
<b>Instrument Name</b> EM360	<b>Clinical Chemistry Analyzer</b>	<b>Instrument ID</b>	<b>601070</b>	

**7.0 EXECUTION OF TEST PLAN**

Precision Study- Run test in 10 replicates & calculate Mean, SD & CV%  
 Accuracy Study- Run QC

**Reviewed by:**

Name	Signature	Date
Ravi Kumar Sah		03-01-2022

TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION FOR DAGAR DIAGNOSTIC CENTER  
PALWAL 121102



Instrument Name EM360	Clinical Chemistry Analyzer	Instrument ID	601070
--------------------------	-----------------------------	---------------	--------

8.0 DEFICIENCIES / DEVIATIONS:

No Deviation

Reviewed by:

Name	Signature	Date
Ravi Kumar Sah		03-01-2022